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Jeffrey Benjamin Esq.
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RE: Douglas J. Horn and Cindy Harp-Horn v. Medical Marijuana, Dixie Elixirs and Edibles, Red Rice Holdings, LLC and Dixie Botanicals

Dear Mr. Benjamin:

As you requested, I have examined copies you provided of the following documents:

1. Statement of James Horn to Elizabeth Horn dated November 23, 2012.

2. Advertisement for Dixie X that appeared in the Fall 2012 Issue of High Times magazine.

3. Laboratory Litigation Package from Clinical Reference Laboratory related to a drug test analysis for specimen ID#2013672889 in October 2012.

4. Press release issued by Dixie Botanicals regarding product quality and efficacy clarification and dated November 26, 2013.

5. Email communications between James Horn and Scott Van Etten (EMSL Analytical, Inc.) dated November 8 and November 26, 2012.

6. Laboratory data and report for product testing order #281201415 issued by EMSL Analytical, Inc. on November 5, 2012.

7. FAQ webpage from Dixiex.com pulled on October 11, 2012.

8. Civil Complaint filed with the U.S. District Court, Western District of New York and dated August 5, 2015.

9. Follow-up SAP evaluation report prepared by Kenneth Dennis, Ph.D. on July 24, 2013.

10. Facebook post of Tamara Wise from November 20, 2013 and expose of Medical Marijuana, Inc. CBD products appearing on beyondTHC.com website.

11. Partial deposition transcript of James Horn dated May 8, 2017.

As I understand the events of this case from these documents, around February 24, 2012, James Horn, a 46-year old commercial hazmat truck driver with Enterprise Transportation for the previous 10 years, injured his hip and shoulder. He returned to work in May, 2012, but, due to lingering discomfort in his shoulder, his family physician treated him with anti-inflammatory and analgesic medications. Mr. Horn did not get the relief he expected from the medications and sought a more natural alternative. As a result, he started to search for a natural product remedy. While on a route in Texas, he read a "Fall 2012" copy of High Times magazine that was on a nearby table while he was having a coffee. In the magazine, he was drawn to the headline "CDB for Everyone" which was an advertisement that promoted Dixie X, described as a cannabidiol (CBD)-rich medicine derived from natural industrial hemp with "0%" THC (the main psychoactive constituent in marijuana). The advertisement further stated that the company, Dixie Elixirs and Edibles, is "importing industrial hemp from outside the US using an FDA import license – it's below the federal guideline for THC, which is 0.3% - and we are taking that hemp and extracting the CBD". The Dixie X product line was commercially launched on September 5, 2012. After conducting some additional internet investigation and based on the information contained in the product advertisement from High Times, Mr. Horn believed that the product could be used by anyone and since it contained no or "0%" THC, his use of the product would not run afoul of U.S. DOT drug testing protocols for which he was subject as a commercial truck driver. Around mid-September 2012, Mr. Horn's wife ordered Dixie X Elixir containing a purported 500 mg CBD. He started using the product at bedtime beginning on October 1, 2012.

On October 9, 2012, Mr. Horn was selected for a random urine drug screen in compliance with U.S. DOT requirements for commercial truck drivers. Mr. Horn's urine sample was analyzed by Clinical Reference Laboratory and the results indicated that his sample screened positive for cannabinoids at a threshold concentration of 50 ng/mL. The sample was subsequently confirmed positive for marijuana metabolite (Carboxy-THC or THC-COOH) at a threshold concentration of 15 ng/mL. The actual concentration of marijuana metabolite in Mr. Horn's urine was quantitated at 29 ng/mL.

On October 11, 2012, Mr. Horn was notified that he failed his urine drug screen since it tested positive for marijuana metabolite. Due to his positive urine drug test, Mr. Horn was terminated from his position by his employer. Since Mr. Horn was not a marijuana user and had no prior history of failing drug screens for marijuana metabolite, he called the supplier from which his wife had ordered the Dixie X Elixir product and the company apparently assured him that there

was no THC in their product, but they would check their batch records and get back to him. Mr. Horn claims the company did not follow-up and refused his subsequent phone calls. He did not take any of the Dixie X Elixir at bedtime on October 11, 2012. The following morning, he located a drug screen office which used a kit to conduct a quick 10-panel screen and then subsequently sent the sample he provided for formal laboratory testing. Both the 10-panel screen and laboratory test results produced negative findings for marijuana metabolite.

When he returned home, Mr. Horn purchased an over-the-counter drug test kit with the intent of validating that the Dixie X Elixir was the source of the positive marijuana urine drug screen finding. He again used the Dixie X Elixir, collected a urine sample following the kit instructions and sent the sample to the indicated laboratory for analysis. The sample apparently tested positive for marijuana metabolite. Mr. Horn then ordered another Dixie X Elixir containing 500 mg CBD from Dixie Elixirs and Edibles with the objective of sending an unopened product to an independent laboratory for analysis of THC content. The company seemingly sent him the 100 mg CBD elixir in error, but, regardless, Mr. Horn decided to send this product to the lab for analysis.

The 100 mg CDB elixir was sent to EMSL Analytical, Inc. for analysis of THC content. The laboratory identified THC in the product at a concentration of 170 µg/g or 170 ppm. Due to the presumed order error, the 500 mg formulation that Mr. Horn actually used was not available for testing by the laboratory.

The Frequently Asked Questions (FAQ) page on the DixieX.com website in October 2012 include the following statements:

> *Our revolutionary Hemp oil cannabidiol (CBD) wellness products are legal to consume both here in the U.S. and in many countries abroad. The United States currently considers industrial hemp products to be legal as long as they are derived from industrial hemp and not from any part of the plant categorized under the United States Controlled Substances Act as marijuana. Dixie X's parent company, Medical Marijuana, Inc., is a publicly traded company that does not grow, sell or distribute any substances that violate United States Law or the controlled substances act.*
>
> *The CBD we use is biologically created in hemp plants and our methodology isolates and extracts it. We then infuse this naturally occurring CBD into our line of hemp products*
>
> *All of our products are tested multiple times during the manufacturing process using both traditional ISO17025 chemical testing facilities, as well as cannabinoid testing facilities, all of which are based in the U.S.*

> *We are not aware of any psychotropic effects associated with using these products. The complete product line of Dixie X is consistently tested throughout the formulation and manufacturing process to ensure it meets all local, state and Federal guidelines and laws.*
>
> *While the two plants (hemp and cannabis) are botanically related, our hemp contains no THC and numerous medical studies have shown CBD to have significant potential health benefits for a variety of ailments ranging from epilepsy to pain management. Medical cannabis contains THC and may provide relief from various ailments, however, with a psychotropic effect.*

On November 21, 2013, Tamara Wise, former chief scientist at Medical Marijuana, Inc. and Dixie Elixirs, made assertions on a blog that denounced the company and the quality of the hemp-based products that were being produced. On November 26, 2013, Dixie Botanicals issued a press release refuting Ms. Wise's assertions and reiterating that the company prides itself on the quality and efficacy of their products and that both their raw materials and final products pass rigorous testing procedures to ensure they meet the highest standards.

You requested that I provide background and opinions on the THC content of Dixie X Elixir, the implications of using this product on a urine drug screen and whether the product complies with federal statutes for controlled substances.

Background

Hemp and Marijuana

Cannabis sativa is the scientific name of the annual herbaceous plant, marijuana or hemp. Since hemp and marijuana are varieties of the same plant species, they mainly differ in their content of cannabinoids. Cannabinoids, some of which are psychoactive in humans are primarily found in leaves and bracts of the mature plant. Among these compounds, delta^9-tetrahydrocannabinol (Δ^9-THC or THC) is the most psychoactive component contributing to the behavioral effects and toxicity of cannabis[1]. The typical average percentage of THC in marijuana is approximately 4 to 20%. In comparison, industrial hemp strains are cultivated to increase the concentration of cannabidiol (CBD) and lower the concentration of THC content. Unlike THC, CBD is not psychoactive. Hemp licensed for farming in the European Union (EU) and Canada must legally be bred to maintain a THC content of less than 0.3% [2, 3]. Federal law in the U.S. currently prohibits commercial farming of any variety of *Cannabis sativa*, but allows for the importation and use of industrial hemp material.

The presence of THC residues in hemp products and the increasing availability of these products to consumers has raised concerns related to both the known pharmacologic effects of THC when ingested and the established potential of the drug to produce positive test results under workplace drug testing programs instituted by many public and private institutions. Carboxy-THC is the major metabolite of THC and serves as the main analytical target in urine drug screens for marijuana exposure. A positive drug test result may cause a loss or rejection of employment.

Several scientific studies[4-10] have shown that ingestion of single or multiple doses of commercial hemp products can cause confirmed positive drug test results for THC. Urine specimens often exceeded the 50 ng/mL screen cut-off and the 15 ng/mL confirmation cut-off levels employed in U.S. Department of Transportation drug screen protocols. Most of these studies were conducted using hemp products that routinely exceeded 50 μg/g (50 ppm) of THC.

Cannabidiol

Cannabidiol is one of over 100 cannabinoids identified in cannabis. It is the major cannabinoid present in industrial hemp and accounts for up to 40% of the extract from the plant. The use of CBD-containing products has gained popularity due to potential anti-epileptic, anti-inflammatory, anti-psychotic and analgesic benefits ascribed to the compound. To date, CBD-containing products have not been approved as drugs by the FDA to treat a specific disease or disease-related symptoms, although Epidiolex®, a product with CBD as the active ingredient, received orphan drug status in the U.S. in July 2015 for the treatment of Dravet syndrome, a rare form of epilepsy that begins in infancy. Cannabidiol is insoluble in water, but soluble in organic solvents. Under acidic conditions, it can cyclize to THC[11]. Several recent studies[12, 13] have demonstrated the formation of THC from CBD in simulated gastric fluid. Once formed in the acidic environment of the stomach, THC can then be absorbed into the bloodstream to exert potential pharmacologic effects or produce a positive urine drug screen finding.

Federal Controlled Substance Implications

Under federal U.S. drug policy (21 U.S.C. §1308.11), marijuana and cannabinoids are categorized as DEA Schedule I controlled substances because they are associated with one or more of the following findings:

- The drug or other substance has a high potential for abuse.
- The drug or other substance has no currently accepted medical use in treatment in the United States.
- There is a lack of accepted safety for use of the drug or other substance under medical supervision

Any material, compound, mixture or preparation that contains any quantity of THC or marijuana extract containing one or more cannabinoids derived from any plant of the genus Cannabis is categorized as a DEA Schedule I controlled substance. There is an exemption (21 U.S.C. §1308.35) to this schedule for cannabis plant material and products made from cannabis plant material that contain tetrahydrocannabinols; however, the products derived from this plant material cannot be used, or intended for use, for human consumption. For this exemption, human consumption means ingested orally or applied by any means that allows THC to enter the body. Intended for human consumption means designed by the manufacturer for human consumption, marketed for human consumption or distributed, exported or imported with the intent that it will be used for human consumption.

Labeling and packaging requirements for controlled substances (21 U.S.C. §1302.03) requires that each commercial container of a controlled substance must contain a label bearing the symbol designating the schedule in which the controlled substance is listed.

If the distribution of a controlled substance is unlawful under 21 U.S.C §801-971, then the mailing of the substance is also a violation under 18 U.S.C. §1716. Controlled substances and products that contain controlled substances are acceptable in the domestic mail only if the mailer and addressee are registered with the US Drug Enforcement Administration (DEA) or are exempted from DEA registration.

Under 21 U.S.C §841, it is unlawful to manufacture, distribute or dispense or possess with intent to manufacture, distribute or dispense a controlled substance. This activity would meet the definition of a continuing criminal enterprise under 21 U.S.C §848 if such a violation is part of a continuing series of violations that are undertaken by a person in concert with five or more persons from which the person obtains substantial income or resources.

Under 15 U.S.C §52, it is unlawful for any person, partnership or corporation to disseminate, or cause to be disseminated, any false advertisement.

Dixie X Elixir

Dixie X Elixir was launched in early September 2012 as a hemp wellness product and CBD-rich medicine that contained either 100 mg or 500 mg of CBD and "0%" THC, suggesting that the product was THC-free. In many states, a "CBD-only" product is defined has having less than 0.3% or 0.5% THC; however, any product containing THC in any amount is considered marijuana under federal law (21 U.S.C. §1308.11) and is illegal. In Marijuana Report (https://www.youtube.com/watch?v=yDjIGXS58ds) and American Weed (https://www.youtube.com/watch?v=Urlwtw_xQ48) radio interviews conducted with Tripp Keber, Managing Director of Dixie Elixirs and Edibles, that were posted on YouTube in August 2012, Mr. Keber described his new product as a dietary supplement or nutraceutical and not

medical marijuana or a THC-infused product. He stated numerous times that Dixie X Elixir contained no THC and the product was tested hundreds of times and showed no THC.

EMSL Analytical, Inc. tested a Dixie X Elixir product containing a claimed concentration of 100 mg CBD. The lab measured THC in the product at a concentration of 170 µg/g or 170 ppm. Since the same CBD extraction process was likely used to formulate the 500 mg CBD elixir, it's reasonable to assume that this product would contain approximately 850 µg/g or 850 ppm of THC.

The label for the Dixie X Elixir did not bear the symbol designating it as a Schedule I substance due to the presence of a measurable quantity of THC in the product.

Opinions

My review and analysis of the records in this case, lead me to conclude the following within a reasonable degree of scientific certainty:

1. The presence of at least 170 ppm of THC measured in a Dixie X Elixir containing 100 mg CBD and, potentially up to 850 ppm of THC in the 500 mg CBD product, significantly exceeds the 50 ppm THC concentration in the hemp products that were used in studies[4-10] that demonstrated the ability of the products to produce a positive THC drug screen result. The use of Dixie X Elixir also has the potential to yield additional THC exposure by conversion of CBD to THC in the acidic environment of the stomach[12, 13].

2. Since there was no evidence that indicated Mr. Horn had a history of either recreational or medicinal marijuana use, Mr. Horn's exposure to THC from his daily use of Dixie X Elixir for eight days preceding his DOT urine sample collection on October 9, 2012 was the direct cause of his positive THC drug test result that subsequently led to his loss of employment.

3. Dixie X Elixir contains a measurable amount of THC. The product was advertised as containing "0%" THC and public statements by the company's managing director stated the product "contains no THC". These claims are contradicted by the presence of THC in the product and represent false advertisement that would be seemingly unlawful under 15 U.S.C §52. Based on these false claims, Mr. Horn had his wife purchase the product believing that he could benefit from the wellness potential of the Dixie X Elixir derived from natural hemp without concern of it producing a positive THC drug test result under DOT drug testing guidelines that were applicable to his employment.

4. Despite recent decriminalization and compassionate medical use laws in some states, marijuana is not a benign drug and remains a Schedule I controlled substance under Federal law.

5. Since a measurable quantity of 170 µg/g (170 ppm) THC was measured by EMSL Analytical, Inc. in a Dixie X Elixir containing 100 mg CBD, the product would be classified as a Schedule 1 substance as described under 21 U.S.C. §1308.11. Although Dixie X Elixir is a product made from cannabis plant material (hemp) that contains tetrahydrocannabinols, it would not be eligible for an exemption to a Schedule I classification under 21 U.S.C. §1308.35 since it is intended for human consumption.

6. Company website content and public statements issued by the managing director denote that Dixie X Elixirs are tested multiple times during the manufacturing process using both ISO17025 compliant testing facilities as well as cannabinoid testing facilities. If the product was actually tested for cannabinoid content during the manufacturing process as claimed, then the results should have shown that Dixie X Elixir contained a measurable quantity of THC which would then classify the product as a DEA Schedule 1 substance under 21 U.S.C. §1308.35. Manufacturing process test results showing the presence of THC in the Dixie X formulation would signify that the advertising and public statements asserting the product contained no THC were false and may be unlawful under 15 U.S.C §52. Alternatively, if the formulation was not tested for cannabinoid content as claimed, the company would lack the knowledge to contend that their product contained no THC.

7. As neither Dixie Elixirs and Edibles nor Mr. Horn were apparently registered with the US Drug Enforcement Administration. the distribution of a Schedule I substance, such as Dixie X Elixir, across state lines would be unlawful under 21 U.S.C §801-971 and, if the product was shipped through the domestic mail system, the distribution would also seemingly be unlawful under 18 U.S.C. §1716.

8. The Dixie X Elixir product label did not bear the symbol reflecting that it was a Schedule I substance and, therefore, violated packaging and labeling requirements under 21 U.S.C. §1302.03.

9. Dixie Elixirs and Edibles manufactured and distributed a controlled substance which is unlawful under 21 U.S.C §841. Since the manufacture and distribution of the Schedule I Dixie X Elixir presumably occurred repeatedly over time, it may constitute a continuing criminal enterprise under 21 U.S.C §848.

10. Since the manufacture and distribution of Dixie X Elixir appears to violate multiple federal statutes, the advertising and public statement claims that the Dixie X Elixirs do not conflict with any federal law and that the parent company, Medical Marijuana, Inc. does not grow, sell or distribute any substances that violate United States Law or the controlled substances act are false and appear to violate 15 U.S.C §52 covering the dissemination of false advertisement.

If you need additional explanation of the concepts involved or have further need of my services, please contact me.

Very truly yours,

Kenneth D. Graham, Ph.D., R.Ph.

References

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